K120246

"510(k) Summary"

AUG 28 2012

510(k) Owner Name	Carestream Health, Inc.
510(k) Owner Address	150 Verona Street Rochester, New York 14608
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Contact Name & Info	Katherine Honsinger Regulatory Affairs Manager katherine.honsinger@carestreamhealth.com
Date Summary Prepared	September 29, 2011
Device Trade Name	Kodak DirectView CR Mammography System
Device Common Name	CR Digital Mammography System
Classification Name	Full Field Digital, System, Xray, Mammographic
Regulation Name	Full-Field Digital Mammography System
Device Class	Class II
Device Code	MUE
Regulation Number	21 CFR 892.1715, Full-Field Digital Mammography System
Predicate Device	Kodak DirectView CR Mammography System (P080018/S001)

Device Description

The Carestream CR Mammography Cassette with SNP-M1 Screen is a structured needle phosphor detector used in conjunction with the Kodak DirectView CR Mammography Feature on Kodak DirectView CR Systems for generating digital mammographic images. The Carestream CR Mammography Cassette SNP-M1 Screen is used in the same manner as a traditional screen-film cassette when performing radiographic patient exposures and will be used in the DirectView CR Systems: CR850, CR950, CR975, Classic CR and Elite CR readers using the Kodak DirectView CR Mammography Feature.

Intended Use
Indications for Use and Intended Use of the modified device remain unchanged from the predicate device.

The Kodak DirectView CR Mammography Feature together with the CR Mammography Cassette comprise a device which, when used in conjunction with a Kodak DirectView CR System and a mammographic X-ray machine, generates digital mammographic images that can be used for screening and diagnosis of breast cancer. It is intended for use in the same clinical applications as traditional screen-film based mammographic systems. The mammographic images can be interpreted by a qualified physician using either hardcopy film or softcopy display at a workstation.

Comparison of Technological Characteristics
The SNP-M1 storage phosphor screen consists of a structured needle phosphor layer. The predicate device EHR-M3 storage phosphor screen consists of a powdered-base phosphor layer. The SNP-M1 needle-shaped phosphor crystals, which are oriented at 90 degrees to the screen surface, reduce the spread of light within the screen, and produce a more uniform screen structure compared to the EHR-M3 powder-based phosphors. The SNP-M1 structured needle phosphor screen with reader optimization kit is designed to provide improved image quality, increased sharpness, and reduced noise, delivered at a lower dose compared to the EHR-M3 powdered-based phosphor screen. Either screen type is adhered to a rigid aluminum cassette plate assembly which is inserted within the cassette housing. There are minor modifications to the cassette housing to protect the SNP-M1 screen/plate assembly from scratching or damage.

As with the EHR-M3 screen, the SNP-M1 screen is used in the same manner as a traditional screen-film cassette when performing radiographic patient exposures and will be used in all DirectView CR Systems: CR850, CR950, CR975, Classic CR and Elite CR readers that utilize the Kodak DirectView CR Mammography Feature. The CR readers are modified to optimize image quality of images captured with the SNP-M1 Screen.

There is no difference in image acquisition. Use and functional operation of the CR Mammography Cassette with SNP-M1 Screen in the CR850, CR950, CR975, Classic CR and Elite CR Readers is the same as that for the predicate device CR Mammography Cassettes with EHR-M3 Screen.

There are no significant changes in the image processing software used with the CR Mammography Cassette with SNP-M1 Screen. The Kodak DirectView CR Mammography Feature utilizing Kodak ECLIPSE Image Processing Software v5.4 is the same as that used with the CR Mammography Cassette with EHR-M3 Screen. A modified looks database enhances the image quality by adjusting noise, contrast, brightness, sharpness and detail of the images captured with the SNP-M1 Screen.

Discussion of Testing
Performance testing was conducted to verify the design output met the design input requirements and to validate the device conformed to the defined user needs and intended uses. Non-clinical physical laboratory testing was conducted to assess performance. Clinical image evaluation was also conducted. Predefined acceptance criteria was met and demonstrated that the device is substantially equivalent to and as safe and as effective as the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

AUG 28 2012

Ms. Katherine Honsinger
Regulatory Affairs Manager
Carestream Health, Inc.
150 Verona Street
ROCHESTER NY 14608

Re: K120246
Trade/Device Name: KODAK DirectView CR Mammography System
Regulation Number: 21 CFR 892.1715
Regulation Name: Full-field digital mammography system
Regulatory Class: II
Product Code: MUE
Dated: August 23, 2012
Received: August 24, 2012

Dear Ms. Honsinger:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely Yours,

Janine M. Morris
Acting Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known):

Device Name: KODAK DirectView CR Mammography System

Indications for Use: The KODAK DirectView CR Mammography Feature together with KODAK DirectView CR Mammography Cassette comprise a device which, when used in conjunction with a KODAK DirectView CR System and a mammographic x-ray machine, generates digital mammographic images that can be used for screening and diagnosis of breast cancer. It is intended for use in the same clinical applications as traditional screen-film based mammographic systems. The mammographic images can be interpreted by a qualified physician using either hardcopy film or softcopy display at a workstation.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

(Division Sign-Off)
Division of Radiological Devices
OIVD
510k K120246